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No. 87-1021

In the Supreme Court of the United States

October Term, 1987

PLAYTEX HOLDINGS, INC.,

Petitioner,

v.

KELLY M. O'GILVIE, Individually and as Administrator of the Estate of Betty L. O'Gilvie, Deceased; and STEPHANIE L. O'GILVIE, a Minor, and KEVIN M. O'GILVIE, a Minor, By and Through Kelly M. O'Gilvie, Their Father and Natural Guardian,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether one who is not a party to the record or judgment for which review is sought may petition the United States Supreme Court for a writ of certiorari.

2. Whether this Court should entertain the petition for writ of certiorari which alleges as grounds for review issues not raised in the proceedings below.

3. Whether the Constitution and federal rules preclude a federal court from substituting its own findings of fact for that of the jury as to the appropriate amount of punitive damages which should be awarded in the absence of a finding that the award was excessive.

4. Whether Courts have the authority to adopt the doctrine of federal preemption to preclude state common-law tort remedies in the face of Congressional intent not to preempt.

PARTIES TO THE PROCEEDING

Petitioner, Playtex Holdings, Inc., was not a party to the record or judgment in the proceedings before the District Court or the United States Court of Appeals for the Tenth Circuit and is not a party to the proceeding by virtue of substitution, intervention, or third party practice. In all other respects, Petitoner's identification of the proper parties to the proceeding is correct.*

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*Respondents have reasonable grounds to believe that Petitioner Playtex Holdings, Inc. is not the legitimate corporate successor to International Playtex, Inc. In at least two other pending TSS cases, another entity, Playtex Family Products, Inc., has been identified as the "successor to the tampon business of International Playtex, Inc." Res. App. 1a-3a. It is perhaps significant that current counsel of record still recognize that International Playtex, Inc. is the proper party to these proceedings and have filed pleadings with the Tenth Circuit Court of Appeals documenting that fact. Res. App. 3a-4a.

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KELLY M. O'GILVIE, Individually and as Administrator of the Estate of Betty L. O'Gilvie, Deceased; and STEPHANIE L. O'GILVIE, a Minor, and KEVIN M. O'GILVIE, a Minor, By and Through Kelly M. O'Gilvie, Their Father and Natural Guardian,

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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BRIEF IN OPPOSITION

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JURISDICTION

As set forth in the Argument below, this Court does not have jurisdiction to review the judgment under 28 U.S.C. § 1254(1) because Petitioner is not a party to the record and judgment below or to these proceedings by way of substitution, intervention, or third-party practice, and Defendant-Appellee below, International Playtex, Inc.,

has failed to petition for certiorari within the time permitted by 28 U.S.C. § 2101(c).

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STATEMENT OF THE CASE

This products liability action was tried to a jury in federal court, pursuant to diversity jurisdiction, to recover damages for the death of Betty O'Gilvie from Toxic Shock Syndrome (TSS) following her use of Playtex Super deodorant tampons.

The case went to the jury on several theories of liability: negligent design, failure to test, and failure to adequately warn; and strict liability for design defect, inadequate testing, and inadequate warning. Res. App. 6a-23a. Despite Petitioner's representation to the contrary, this case was not solely a warning case. Abundant evidence was introduced that persuaded the jury that Playtex Super deodorant tampons[1] were defective as designed, tested and sold as well as defective for a failure to adequately warn.

Based on substantial, competent evidence that Playtex "deliberately disregarded" scientific evidence that superabsorbent tampons increase the risk of TSS and "deliberately sought to profit" from that fact by advertising

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[1]Playtex Super tampons were constructed of certain superabsorbent fiber components (polyacrylate). The weight of the evidence showed that superabsorbent tampons increase the risk of TSS, a fact known to Playtex which chose to take no action to either decrease the risk of TSS or warn consumers of the increased risk associated with superabsorbency.

that the Playtex tampon was better because more absorbent, the issue of punitive damages was allowed to go to the jury. Pet. App. 14a-15a. The jury found for Respondents and awarded $1,525,000 in compensatory damages and $10 million in punitive damages.

Defendant Playtex filed post-trial motions for judgment notwithstanding the verdict and remittitur on the grounds that the evidence did not support the verdict and that the punitive damages were excessive on their face because $10 million was too much regardless of the facts supporting liability for punitive damages.[2]

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[2]Defendant Playtex moved for directed verdict at the close of Plaintiff's evidence and moved for reconsideration of that motion at the close of all the evidence, both of which were denied by the Court. Neither motion challenged the propriety of the issue of punitive damages going to the jury except on the grounds of insufficiency of the evidence to support a finding of willful, wanton conduct in reckless disregard of the safety of others. None of the issues in this Petition were raised before the trial court. Likewise, Defendant Playtex did not challenge the propriety of the jury instructions regarding the effect of Defendant's compliance with FDA regulations other than to state that the evidence was insufficient that Playtex should have done more. Playtex' post-trial motions merely reiterated their earlier position on these issues and requested remittitur on the grounds that $10 million dollars was excessive in light of the evidence and "shocks the conscience." Res. App. 25a. Playtex made no attempt to challenge the punitive damage award on constitutional grounds in the district court or on appeal except to devote one sentence to the issue: "To allow judgment greater than the maximum criminal award without the more stringent standard of proof applicable to a criminal action will result in a seizure of Playtex property without due process of law." Brief of Defendant-Appellee, Cross-Appellant on Appeal to the Tenth Circuit Court of Appeals, p. 43.

The trial court denied Playtex' post-trial motions, but offered a "provocative proposition" to the company.[3] The Court stated that if the President of Playtex would come into his courtroom, acknowledge the facts were as the jury found them, and take the Playtex Super tampons off the market, the Court would substantially reduce or eliminate the punitive award. The company did not make any admissions, of course, but did subsequently remove their superabsorbency tampons from the market. The trial court thereafter remitted the punitive award from $10 million dollars to $1,350,000.00. Pet. App. 37a.

From the remittitur, Respondents appealed and International Playtex, Inc., cross-appealed the judgment as a whole. The Tenth Circuit upheld the jury verdict in its entirety and reversed the trial court's remittitur of punitive damages on the grounds that, in the presence of a finding the award was not excessive, the trial court could not remit the award based on post-trial conduct of the defendant. Pet. App. 1a-36a. In fact, the Tenth Circuit found that contrary to the trial court's intent of encouraging remedial action, the remittitur "subverts the goals of punishment and deterrence" by "rewarding the company for continuing its tortious conduct long enough to use it as a bargaining chip in the remittitur proceedings." Pet. App. 22a-23a. Defendant-Appellee International Playtex, Inc. petitioned the Tenth Circuit for a rehearing en banc.

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[3]The trial court made the specific finding that the award was not excessive and did not shock the conscience. While acknowledging he was without authority to remit the award except on the grounds of excessiveness, the trial judge determined that if Playtex would accept his "provocative proposal," he would reduce the punitive award. Res. App. 25a-29a.

The petition for rehearing raised no constitutional issues whatsoever and, as Petitioner concedes, the preemption issue has never been raised at any point prior to the filing of the petition for writ of certiorari. Pet. 5, fn. 5.

Following the ruling of the Tenth Circuit Court of Appeals, Playtex Holdings, Inc., a stranger to the proceedings below, filed a petition for writ of certiorari. At no time prior to the filing of this petition has any substitution or intervention of parties been sought or accomplished by this entity. Petitioner alleges in a footnote to its petition that it is a successor corporation to International Playtex, Inc., but as Respondents set forth in their opposition, such a "notice" by a successor party cannot bestow upon it a right to appeal the decision of the Tenth Circuit Court of Appeals.

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SUMMARY OF ARGUMENT

Certiorari should be denied because a) Petitioner is not a proper party to the proceeding and lacks entitlement to review the decision of the Tenth Circuit Court of Appeals; b) Defendant-Appellee below waived all of its constitutional arguments and its preemption argument by failing to object to jury instructions and, in fact, proposing instructions that were squarely inconsistent with those arguments; c) the Defendant-Appellee below failed to present its eighth amendment argument and preemption argument in a timely manner, as required by consistently applied federal practice; d) the decision below is not even alleged to be in conflict with any other decisions of this

Court or the other circuit courts of appeal; and e) there is no urgent reason, in the context of this case, for the Court to resolve these constitutional questions which implicate important and long-standing state interests.

The eighth amendment and due process challenges to punitive damage awards Petitioner attempts to raise here are not novel legal theories. They have been raised without success in numerous lower courts over the past two decades. In this case, Defendant-Appellee deliberately chose not to raise its eighth amendment challenge or preemption defense at *any* stage below, and it chose not to raise any of its due process challenges at trial. Instead, Defendant-Appellee attempted to raise its preemption challenge for the first time in a supplemental letter filed *after* its petition for rehearing in the Tenth Circuit. That court declined to consider the belatedly urged claim without comment.

This Court has previously noted that the applicability of the eighth amendment and the due process clause to punitive damage awards raises important questions that "*in an appropriate setting,* must be resolved." *Aetna Life Insurance Co. v. Lavoie*, 106 S.Ct. 1580, 1589 (1986) (emphasis added). But this is not an appropriate setting in which to consider those questions.

That is the lesson of *Judy's Foods, Inc. v. A & B Food Services Corporation*, 107 S.Ct. 460 (1986), which was decided after *Lavoie*. There, as here, Petitioners asked the Court to consider the applicability of the due process clause (and the eighth amendment) to a punitive damage award. The Respondents argued that those questions were not appropiate for review because they had been raised for the

first time in supplemental post-argument briefs in the highest court below. The Petitioner has suggested no reason why review would be more appropriate here despite the fact there is no jurisdictional bar. Pet. 17, fn.23.

Defendant-Appellee below also waived two of its arguments—its challenge to the preponderance of the evidence standard and its challenge to the jury's consideration of Plaintiff's claims of inadequate warning—by failing to object to jury instructions that were squarely inconsistent with those arguments.

Furthermore, even if Defendant-Appellee had raised its constitutional claims below in a timely manner, certiorari would still be inappropriate. The decision below is not even alleged to be in conflict with any other decision, state or federal, and is not inconsistent with prior decisions of this Court. To the contrary, none of Petitioner's constitutional arguments have been adopted by any court, and most of them have been rejected by several lower courts. Moreover, Petitioner relies largely on policy arguments in urging this Court to overturn that substantial body of case law. These same policy arguments are being actively considered by many state legislatures.[4] In these circumstances, the Court need not and should not reexamine this uniform body of case law to consider a constitutional resolution of issues that are currently being addressed through the legislative process.[5]

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[4]*The Economist,* Aug. 1, 1987, at 29 (in recent years 41 states have modified their tort systems and the rest are considering changes).

[5]Punitive damage awards have a two-century history in state tort law. For years, no one questioned the constitutional-

(Continued on following page)

For the same reasons, Petitioner's preemption argument should not be considered. It has no legitimate support in the law and was not raised at any reasonable time before the lower courts.

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ARGUMENT

I.

PLAYTEX HOLDINGS, INC. IS NOT A PARTY TO THE RECORD OR JUDGMENT IN THE CASE OF O'GILVIE V. INTERNATIONAL PLAYTEX, INC., AND THEREFORE IS NOT ENTITLED TO PETITION FOR A WRIT OF CERTIORARI TO OBTAIN REVIEW OF SAID JUDGMENT

It is so well-settled by this Court that only a party to a record and judgment is entitled to appeal therefrom that the subject is no longer open to discussion. In federal decisions dating to the birth of this nation, the Supreme Court and its lesser federal tribunals have staunchly adhered to this rule of law and routinely dismissed appeals and writs of error when a stranger to the record has attempted to invoke their appellate jurisdiction. The rule is so deeply imbedded in the fabric of the federal rules and case law that it requires no exposition. The Petitioner

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(Continued from previous page)

ity of such awards. In recent years, the insurance industry has launched an aggressive campaign in legislatures and courts to restrict punitive damage awards. Although dressed in constitutional clothes, that campaign is based largely on policy arguments. For example, Petitioner argues extensively on the need for tort reform. Pet. 8-9. Those arguments are best addressed by the legislative process.

herein occupies the position of a stranger to the record and judgment of the case it brings to this Court for review and its petition for writ of certiorari must be denied.

Less than two months ago, this Court had occasion to reaffirm this long-standing rule in *Karcher v. May:*

> One who is not an original party to a lawsuit may of course become a party by intervention, substitution, or third party practice. [citation omitted]. But we have consistently applied the general rule that one who is not a party or has not been treated as a party to a judgment has no right to appeal therefrom. [citations omitted]

Karcher v. May, 108 S.Ct. 388 (1987). See also *Bayard v. Lombard,* 50 U.S. 530, 551 (1850); *United States v. Seigel,* 168 F.2d 143 (8th Cir. 1948); *First Iowa Hydro Elec. Coop. v. Iowa-Illinois Gas & E. Co.,* 245 F.2d 630 (8th Cir. 1957); *United States v. LTV Corp.,* 746 F.2d 51 (D.C.Cir. 1984).

Playtex Holdings, Inc. was not a party to the judgment complained of and has made no attempt to become a party to the litigation. Its first and only appearance in the case is to petition this Court for a writ of certiorari in an attempt to reverse the ruling of the Tenth Circuit Court of Appeals upholding the jury verdict below. Under the unequivocal rules of appellate procedure, Petitioner has no entitlement to seek review of the ruling of the Tenth Circuit.

The Circuit Courts of Appeal have had frequent occasions to address the situation at bar. In *United States v. Seigel,* 168 F.2d 143 (8th Cir. 1948), the District of Columbia. Court of Appeals was presented with a fact situation virtually identical to the appellate posture of this case.

After a thorough recital of the district court and appellate rules of procedure,[6] the court dismissed the appeal, stating as follows:

> It has long been settled that one who is not a party to a record and judgment is not entitled to appeal therefrom. . . . We have found no case, and the United States has cited none to us, in which a person who had taken no steps to become a party to the proceeding in the Court below, was permitted to appeal. The decisions dealing with that situation are, as we have indicated, contra the right to appeal.
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> * * *
>
> A person who has not submitted himself to the jurisdiction of a court, and who has not presented to the court his claim of interest in the controversy, ought not to be allowed to appeal from the judgment. The slightest regard for an orderly adjudication of contesting rights dictates that conclusion. The Su-

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[6]The Court of Appeals addressed itself to the effect of both Rule 73(a) of the Federal Rules of Civil Procedure which provides "a party may appeal", and Rule 17(a) which provides "Every action shall be prosecuted in the name of the real party in interest." The court reiterated that all the cases holding that not only parties to the record but also their privies may appeal if the action affects the person's interest, dealt with situations concerning the right to intervene. The court noted that the issue was not whether the appellant had an appealable interest but whether he had taken steps to become a party to the proceeding. Such is the situation in this case. Respondent does not dispute that if, in fact, Playtex Holdings, Inc. was a legitimate corporate successor to the Defendant below, Petitioner had a right to move for substitution as a real party in interest in the Court below. It was not required to do so, however, in order to pursue its appeal as the appeal could have continued in the original party's name. See Fed.R.Civ.P. 25(c) and Fed.R.Civ.P. 43. Nevertheless, "whether it was a refusal or an inadvertent failure", Petitioner is not excused from compliance with "a clear and reasonable rule of procedure for either of those reasons." 168 F.2d, at 147.

> preme Court, in the cases we have cited, thought this matter important.
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> * * *
>
> [The appellant] did not at any time submit itself to the jurisdiction of the court below, or seek to invoke what it now claims to have been its plain rights. It simply asserted itself as a party and acted accordingly. The court cannot, by ignoring or waiving requirements otherwise applicable and based upon sound and important principles of judicial proceedings, extricate it from the position in which it has placed itself. The protection of its claims was its responsibility. It had a plain course of action protective of its rights. It should have pursued it.

United States v. Seigel, 168 F.2d 143, 144-145, 146-147.

Neither can the Petitioner seek review in this Court by application to substitute itself for the original party to the litigation. No provision for such a procedure exists and the rules of appellate procedure mandate that if a substitution or intervention is desired for purposes of appeal, a motion to that effect must be made within the time limitation for filing an appeal. Fed.R.Civ.P. 24; Fed.R.Civ.P. 4(a); *United Airlines, Inc. v. McDonald*, 432 U.S. 385, 392 (1977).

From the foregoing, it is abundantly clear that no "case or controversy" is before this Court as required by Article III of the Constitution and the Petition must be denied for want of jurisdiction. For reasons unknown to Respondent and irrelevant to this Court's determination of the jurisdictional question, the non-prevailing party below, International Playtex, Inc., failed to petition this Court for review of the decision of the Tenth Circuit Court of Appeals within the statutory time limitation of ninety

days imposed by 28 U.S.C. § 2101(c). Such failure deprives this Court of jurisdiction to review the judgment below.

II.

THIS COURT SHOULD NOT CONSIDER THIS PETITION AS IT SEEKS REVIEW ON GROUNDS NOT RAISED AT ANY POINT IN THE PROCEEDINGS BELOW

With only passing comment, Petitioner states there is no bar to this Court considering the issues raised for the first time in its Petition. Respondent readily concedes that in exceptional circumstances, this Court has chosen to hear important federal questions raised for the first time in an appeal or petition for certiorari. Nevertheless, those exceptional circumstances are not present in this case, and the posture of the case before this Court does not warrant departure from this Court's "normal policy of not considering issues which have not been presented to the Court of Appeals and which are not properly presented for review here." *Neely v. Martin K. Eby Construction Co.*, 386 U.S. 317, 330 (1976).

Only one of the questions presented by Petitioner in its petition was even mentioned at any stage of the proceedings below. In its appellate brief to the Tenth Circuit, Playtex devoted one sentence to a purported constitutional issue that judgment greater than the maximum criminal award violated due process. See fn. 2. No mention was made or argument raised that the punitive award was an excessive fine violative of the eighth amendment. Likewise, no argument was made that due process requires judges, not juries, to determine the amount of punitive damages. As Petitioner concedes (Pet. 5, fn. 5) federal

preemption has not been mentioned or raised below. Given the state of the record in these proceedings, no circumstances exist justifying a departure from this Court's general rule not to hear issues not raised in the Courts below.

Respondent has discovered only a handful of diversity cases in which this issue has arisen. In none of them has this Court chosen to exercise its discretion and decide questions not raised in the federal courts below.[7] Of those cases which have permitted review, the Court has found exceptional circumstances justifying departure from the normal policy such as agreement of the parties or the issue had been fully briefed and argued in the Court of Appeals. *City of Oklahoma City v. Tuttle*, 471 U.S. 808 (1985). Of more persuasive value is *City of Springfield, Mass. v. Kibbe*, 107 S.Ct. 1114 (1987). Although a case brought under federal law (§ 1983), the Court specifically refused to hear the appeal, stating that the general rule to decline review "has special force" where the party seeking review proposed and accepted jury instructions contradictory to his position on appeal. Such is the situation in this case

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[7]See *Miree v. DeKalb County, Ga.*, 433 U.S. 25 (1977), and *Neely v. Martin K. Eby Const. Co.*, 386 U.S. 317 (1967). In *Carlson v. Green*, 446 U.S. 14 (1980), the case cited by petitioner, federal jurisdiction was based on 28 U.S.C. Sec. 1331(a). It was a *Bivens* action asserting violations of various constitutional rights. The issue was addressed only in a footnote, in which the Court noted the respondent had no objection to the questions being decided by this Court. In contrast, see *E.E.O.C. v. Federal Labor Relations Authority*, 476 U.S. 19 (1986) where the Court refused to depart from its normal practice and permit review. Absent "exceptional circumstances," the Court does not depart from its normal practice of denying review. *California v. Taylor*, 353 U.S. 553 (1957). *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970). See also *FTC v. Grolier, Inc.*, 462 U.S. 19 (1983); *Rogers v. Lodge*, 458 U.S. 613 (1982).

and this Court should decline review of the questions presented in the petition.[8]

Playtex never argued that it was entitled to judgment as a matter of law on the basis of compliance with FDA regulations nor sought an instruction to that effect.

III.

THE TRIAL COURT HAD NO AUTHORITY TO REMIT THE PUNITIVE DAMAGES AWARD IN THE ABSENCE OF A FINDING OF EXCESSIVENESS

A. Under federal law, disputed factual issues must be determined by the jury.

The main issue raised by this petition for certiorari is whether a federal judge has the authority to substitute his own findings of fact for those of the jury as to the appropriate amount of punitive damages which should be awarded. This inquiry arises in the context of remittitur by the trial court of the punitive damages awarded by the jury from $10 million to $1,350,000.00. Pet. App. 37a. The basis of this remittitur was a judicial bargaining session between International Playtex, Inc., the defendant, and the trial judge. The court specifically ruled that the $10 million award was not excessive, did not shock the conscience,

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[8]At trial, the defendant's only challenge to sending the issue of punitive damages to the jury was inadequate evidence of wanton misconduct. Playtex specifically requested an instruction setting forth the standards of proof for all issues as a preponderance of the evidence. Res. App. 30a-31a. Playtex also requested instructions on the effect of compliance with FDA regulations which paralled the current Kansas law (Res. App. 31a-32a), and a special jury question on punitive damages setting forth the Kansas standard for punitive liability. Res. App. 35a.

and was justified, given the nature of defendant's wrongdoing and the evidence of defendant's profits from its defective product. Pet. App. 55a.

Nevertheless, the trial judge made a "provocative proposition" to Playtex—come into my courtroom and admit your product is defective, take your product off the market, and I will substantially reduce or eliminate the punitive award. Pet. App. 39a. The corporation never made the admission but did withdraw all of their polyacrylate tampons from the market and amended the warning to reflect the jury's finding that a more definite statement was required that tampons contribute to cause TSS. Based on these post-trial developments, the trial judge remitted the punitive award on the grounds that they were mitigating factors he was entitled to consider in assessing the amount appropriate to punish and deter. What the trial court failed to appreciate was that its use of post-trial mitigatory conduct as a "bargaining chip" for remittitur has the effect of encouraging, rather than deterring, wrongful conduct by defendants. Such a procedure provides defendants incentive to persist in wrongful conduct until after a punitive award is returned in the justified hope that post-trial remedial conduct will wipe out the award. This is the view taken by the Tenth Circuit and is one well grounded in marketplace reality.

Thus, we have a situation where a trial judge has substituted his own judgment as to the amount necessary to punish and deter for that of the jury, not on the time-honored rationale that the amount is excessive, but on the court's belief that deterrence has been achieved. This reasoning ignores one of the fundamental purposes of exemplary damages. These damages serve as an example to

others and aids in deterring like misconduct. This purpose is a legitimate one that cannot be achieved through judicial bargaining with the punished defendant. On the contrary, the remittitur serves to encourage others to like conduct in order to have a post-trial bargaining tool.

The remittitur of the trial court in this case must therefore be disapproved on two grounds. One, it deprives exemplary damages of one of its most important purposes —deterrence by example to others, and it invades the province of the jury as a fact finder.[9]

Of greatest significance in this case is the Petitioner's apparent desire to have this court put in place federal common law that states must apportion to judges, not juries, the function of determining amounts of punitive damages under the guise of determining the propriety of the trial court's remittitur in this case. Such a comprehensive revision of the civil justice system is unjustified not only in the context of this case, but also as a matter of balancing state and federal sovereignty.

Congress has to date declined to legislate in the area of state common law remedies generally and in regards to punitive damages specifically, except when a federal remedy is enacted supplanting the state system. Heretofore long-standing and unbroken precedents of the United

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[9]There is no dispute that a federal court may, in certain limited circumstances, intrude on the jury's function and remove issues from their consideration such as on a motion for directed verdict. *Herron v. Southern Pac. Co.*, 283 U.S. 91 (1931). This case does not involve a situation where the federal rules of procedure permit a court to act where state rules would not. There is no conflict between state and federal law present in this case as neither permit judges to resolve disputed factual issues. Fed.R.Civ.P. 38 and 39.

States Supreme Court hold that only states have the power to distribute the functions of its judicial machinery and to determine their own substantive law regarding civil rights and remedies.[10]

Petitioner, and other commentators on the law, suggest that exemplary damages are "different" because they resemble criminal fines or civil penalties. But this suggestion fails to take into consideration the most obvious and glaring dissimilarities between criminal fines and punitive damages. Conviction of crimes analogous to the harm inflicted in the present case such as manslaughter, mayhem, or assault and battery, all carry sanctions beyond anything remotely applicable to a civil judgment. A civil defendant is never exposed to incarceration, loss of the right to earn a livelihood, or divested of his rights as a United States citizen.

The law in this country has never viewed property rights as entitled to the same due process protections as the rights to life and liberty. See *Tull v. United States*, 107 S.Ct. 1831 (1987). For this reason, the standards of proof for criminal and civil cases may vary without violation of due process or equal protection rights. *United*

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[10]If federal courts assume the authority to dictate to the states a citizen's remedies vis-a-vis punitive damages, no logical barrier exists to extending this exercise of legislative power by the judiciary to other substantive state law issues, be they remedies or rights. This court would not reasonably consider itself to have the power to prevent private citizens from claiming damages for pain and suffering, mental anguish or loss of the enjoyment of life. Like punitive damages, such damages are factual determinations that cannot be reduced to objective figures as "out of pocket" expenses and are not susceptible to mathematical formulas. Further, arbitrary legislative limits or "caps" on such damages would raise serious equal protection problems.

States v. Regan, 232 U.S. 37, 47 (1914). Likewise in *Tull*, this court recognized that Congress has the power to fix civil penalties and to delegate functions between the judge and the jury. 107 S.Ct. at 1840. What this Court notably did not say was that the *judiciary* has the power to encroach on the legislative function and reassign the functions of judge and jury in either the federal or state civil justice systems. *Tull* recognized Congressional authority to do so and interpreted the pertinent legislation as delegating to the trial judge the job of determining the amount of a civil penalty within the parameters established by Congress.

Petitioner relies heavily on an argument that federal courts can disregard state procedural law and substitute their own procedural rules in diversity cases. This argument, however, ignores the fact that federal procedural rules allocate the function of determining the proper amount of damages to juries, not judges. Fed.R.Civ.P. 38. *Atlantic & Gulf Stevedores, Inc. v. Ellerman Lines, Limited*, 369 U.S. 355 (1962). The Supreme Court certainly cannot direct states to abandon their own rules of allocating judicial function and require judges to determine the amount of damage awards. Such an action would violate the principle of comity between state and federal systems and vitiate the rule of *Younger v. Harris*, 401 U.S. 37 (1971).[11] Congress has not conferred on judges the authori-

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[11]The principles of comity require "a proper respect for state functions, a recognition of the fact that the entire country is made up of a Union of separate state governments, and a continuance of the belief that the National Government will fare best if the States and their institutions are left free to perform their separate functions in their separate ways." 401 U.S. 37, 44

(Continued on following page)

ty to determine the amount of punitive damages nor has Kansas law. On the contrary, Congress has reserved the fact-finding function to juries alone. Fed.R.Civ.P. 38.

Kansas law also allocates damages issues to juries and is constitutionally free to do so. This Court has heretofore consistently held that the federal system assigns the decisions of disputed questions of fact to the jury "under the influence—if not the command—of the Seventh Amendment . . ." *Byrd*, 356 U.S., at 901.

The determination of the appropriate amount of punitive damages turns on several factual issues. The basic inquiry is what amount would serve to punish the defendant and deter others from like conduct. Under both federal and Kansas law, the jury may consider the financial resources of a defendant in fixing the amount of punitive damages. By necessity, the conclusion of what amount will punish and deter involves several factual determinations such as the egregiousness of defendant's conduct, the amount of gain attributable to the wrongful conduct, and what amount sufficiently stings a corporate defendant so as to get its attention and induce abandonment of the wrongful conduct. As Blackstone aptly observed "what is ruin to one man's fortune, may be a matter of indifference

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(Continued from previous page)

(1971). The *Erie* doctrine likewise necessitates that federal courts cannot intrude in this area and must apply state law. *Hanna v. Plumer*, 380 U.S. 460 (1965); *Erie v. Tompkins*, 304 U.S. 64, at 74-75 (1938). The cases cited by defendant do not contradict this principle. *Tull* and *Byrd v. Blue Ridge Cooperative*, 356 U.S. 525 (1958) stand for the proposition that the seventh and sixth amendments do not preclude state or federal governments from legislating the allocation of judicial functions.

to another's." 4 W. Blackstone, Commentaries on the Law of England, *377-78 (1768).

In the century following the enactment of the seventh and eighth amendments, this court continued the rule that punitive damage awards have "been always left to the discretion of the jury, as the degree of punishment to be thus inflicted must depend on the particular circumstances of each case." *Day v. Woodworth,* 54 U.S. 363, 371 (1851).

It is thus evident that federal law requires that the factual determination of the amount of an exemplary award be made by the jury. The authority, indeed the obligation, of a judge to review the award when a challenge of excessiveness is made is not disputed. What is at issue is the encroachment of the judiciary on the heretofore inviolate province of the jury to decide facts. Viewed in the necessary perspective of history and precedent, it is evident that this court lacks the authority to remove the fact-finding function from the jury in determining the amount of punitive damages.

B. The Punitive Damage Award In This Case Does Not Violate the Due Process Clause of the Fifth Amendment or the Excessive Fines Clause of the Eighth Amendment.

The issue of whether punitive damage awards violate due process has been briefed and argued to this court extensively. *Bankers Life & Casualty Co. v. Crenshaw,* No. 85-1765 (argued November 30, 1987); *Hawkins v. Allstate Insurance Co.,* 733 P.2d 1073, *cert. denied,* 108 S.Ct. 212 (1987). Respondent will not burden the court with a lengthy recital of the law and arguments already advanced in this court by others. However, there are various issues

bearing on the due process question which have not been addressed by predecessor litigants or raised by this court in oral arguments which are of such grave significance as to warrant careful consideration by this court. Petitioner has chosen to delete from its petition any argument or case authority on the constitutional issues contained in its statement of questions presented and simply refers this court to the issues already raised in the *Bankers Life* case currently pending in this court. Respondents would suggest that citation to the briefs and arguments of parties in unrelated matters is not sufficient to adequately raise an issue for review by this Court. Therefore, Respondents will not address issues not specifically raised by Petitioner.

The foundational arguments in all the recent attacks on punitive damage awards are that such awards constitute excessive fines violative of the eighth amendment and, in the absence of legislative guidelines on the parameters for such awards, constitute deprivation of property without due process. Petitioner herein, however, has chosen to specifically limit its challenge to the punitive award in this case to the question of "whether the Excessive Fines Clause of the Eighth Amendment or the Due Process Clause of the Fifth Amendment generally prohibits the award of punitive damages grossly in excess of comparable criminal penalties." Pet. 14. Respondent will therefore limit its argument to only this one issue properly framed in the Petition.

The sole basis for Petitioner's constitutional challenge to the punitive damage award below is that it grossly exceeds comparable criminal penalties. Pet. 4-5, 14. Re-

spondents respectfully submit that Petitioner's view of "comparable" penalties is myopic at best. The circumstances of this case involve the death of a young mother as the result of her use of the product manufactured by International Playtex, Inc. The Tenth Circuit Court of Appeals found there was "abundant evidence" to support the jury's finding that Playtex' conduct was a willful and wanton invasion of plaintiff's rights and evidenced a "reckless indifference to consumer safety." Pet. App. 14a-15a. These facts satisfy the statutory definition of involuntary manslaughter in the State of Kansas.[12] Of greater than passing interest is the fact that the Kansas standard for imposing punitive damages is more strigent than the elements for manslaughter which do not require a willful or intentional act. The punitive damage standard does require a finding of willful misconduct. *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038, at 1061 (1984). Given the nature of the wrong involved in this case and the severity of the injuries suffered by victims of Toxic Shock Syndrome, manslaughter, mayhem, and battery are far more analogous crimes than a business tort or a violation of Food, Drug, and Cosmetic Act mislabeling provisions, such as Petitioner proposes would be "comparable".

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[12]K.S.A. 21-3404 defines involuntary manslaughter as follows:

> (a) Involuntary manslaughter is the unlawful killing of a human being, without malice, which is done unintentionally in the wanton commission of an unlawful act not amounting to felony, or in the commission of a lawful act in an unlawful or wanton manner.

Under this statutory definition, the conduct of Playtex constituted the crime of involuntary manslaughter.

The penalties for these crimes of injury to persons are set forth in K.S.A. 21-4503 which sets the fines for all felonies and misdemeanors. The minimum fine for involuntary manslaughter, the crime most analogous to the situation in this case, is Ten Tousand Dollars. However, the statute has a provision for an alternative fine as follows:

> (3) As an alternative to any of the above fines, the fine imposed may be fixed at any greater sum not exceeding double the pecuniary gain derived from the crime by the offender. Res. App. 36a-37a.

This provision clearly evidences a recognition by the Kansas legislature that wrongful conduct which bestows pecuniary gain on the wrongdoer warrants greater penalties than the minimum statutory fine, and establishes that the punitive award of the jury was not grossly disproportionate to the comparable criminal penalty.[13] This was the only basis for Petitioner's allegations that the punitive award violated the excessive fines clause or due process clause. As has been illustrated, the argument of "disproportionality" fails under rational scrutiny. The criminal

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[13]The law has long recognized the power of sovereigns to deprive a citizen of ill-gotten gains. No one would seriously contest the constitutionality of laws which permit governments to seize property which has been used in the commission of a crime or obtained from profits from unlawful activities. Punitive damages represent the same principle at work in the civil justice system. Individuals or corporations who realize pecuniary gain from wanton and willful tortious activity are, and should be, subject to the same risk of forfeiture of those gains. Punitive damages fulfill this function in civil matters and thus further a legitimate goal and policy of the law that persons should not be permitted to profit from their own wrongdoing. This function is subsumed in the goal of punishment and deterrence for which punitive damages were created.

penalty would have permitted a fine far in excess of the punitive damages actually awarded.

This court has long held the view that deprivations of property do not warrant the same procedural safeguards as deprivations of life or liberty. A civil trial satisfies all the necessary elements of procedural due process the law requires. *Parratt v. Taylor*, 451 U.S. 527 (1981) and *Board of Regents v. Roth*, 408 U.S. 564 (1972). No case has ever held, and Petitioner cites none, to the effect that criminal standards of proof and other constitutional safeguards should apply to deprivations of property. See *Herman & Maclean v. Huddleston*, 459 U.S. 375 (1983); *Sedima v. Imrex Co.*, 473 U.S. 479 (1985).[14]

Throughout the recent discourse on the history and jurisprudence informing the current law on punitive damages, the character of these damages as "quasi-criminal" is greatly stressed. Respondents would submit that it is not the goal advanced by any deprivation, be it in a civil or criminal context, but the nature of the right of which a person is deprived that determines the level of due process required. Whether some may choose to label the goal

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[14]Such a holding would be dangerous precedent indeed. The natural evolution of such a doctrine raises the grim specter of full-blown evidentiary trials prior to state or federal deprivations of virtually all protected property interests which a litigant could successfully label as punitive. Dismissal of a state university tenured professor for cause is "punishment" for misconduct. The imposition of a civil liability for any tortiously inflicted injury has always been viewed as a deterrent of wrongful conduct. "It is almost axiomatic that the threat of damages has a deterrent effect." *Carlson v. Green*, 446 U.S. 14, 20 (1980). See also *Imbler v. Pachtman*, 424 U.S. 409, 442 (1976) (White, J., concurring in judgment). Under Petitioner's rationale, all damages awards or civil penalties would be subject to the same due process safeguards afforded criminal sanctions as they all share the goal of deterrence and punishment to some degree.

of civil damages as a deterrent, a punishment, or compensation, it must, in this context, be irrelevant. It is the right deprived that triggers the full panoply of due process rights not whether one chooses to label the penalty punitive or compensatory.

Under Petitioner's reasoning, no civil penalty could be imposed without proof beyond a reasonable doubt and every other Constitutional protection afforded to criminal defendants. This court has always held that civil penalties may be imposed without the rigorous standards governing criminal proceedings. *Tull v. United States*, 107 S.Ct. 1831 (1987). Due process has been served in this case. If the mechanism by which exemplary damages are awarded is to be changed it must be through the exercise of the legislative prerogative. Tort reform is best left to the legislatures who possess the constitutional authority to determine the rights and remedies of citizens in the civil justice system.

The only challenge by Petitioner to the punitive award as an excessive fine was in the context of its due process argument. Pet. 4-5. Respondents will not separately address the law on the excessive fines clause of the eighth amendment as it has not been raised by Petitioner.

IV.

NO STATE COMMON LAW REMEDIES ARE PREEMPTED BY FEDERAL LAW IN THIS CASE

The doctrine of federal preemption is a highly complex legal issue to which exhaustive treatment has been given by all federal courts. Most pertinent to the inquiry here, however, is the fact that the federal agency charged with enforcing the congressional legislation Petitioner

claims preempts a common law remedy in this case, has specifically found that 21 U.S.C. § 360k does not preempt state tort remedies. In an official Advisory Opinion issued in 1984, the Federal Food and Drug Administration (FDA) stated as follows:

> There is no indication in the legislative history of 521(a) that Congress intended that the section preempt state or local requirements respecting general enforcement, including available legal remedies, or state or local statutes that only incidentally apply to devices. Rules or requirements established by states to govern the legal remedies available under the state judicial system are not "requirements with respect to a device" within the meaning of § 521 (a) of the act. Res. App. 38a-40a.[15]

This Court has always viewed an administrative agency's construction and application of a statute as entitled to "substantial deference". *United States v. Rutherford*, 442 U.S. 544 (1979). Such determinations by an agency are subject to review only to determine whether the administrator has exceeded his statutory authority or acted arbitrarily. *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691 (1984).

Even in the absence of this clear directive from the FDA, this Court has consistently held that state tort law coexists with even extensive federal regulation. As stated in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984):

> No doubt there is tension between the conclusion that safety regulation is the exclusive concern of the fed-

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[15]Section 521(a) of the Federal Food, Drug, and Cosmetic Act is found in the U.S. Code at 21 U.S.C. § 360k, and is the provision Petitioner contends preempts Respondent's state tort remedies.

> eral law and the conclusion that a State may nevertheless award damages based on its own law of liability. But as we understand what was done over the years in the legislation concerning nuclear energy, Congress intended to stand by both concepts and to tolerate whatever tension there was between them. We can do no less. It may be that the award of damages based on the state law of negligence or strict liability is regulatory in the sense that a nuclear plant will be threatened with damages liability if it does not conform to state standards, but that regulatory consequence was something that Congress was quite willing to accept.

464 U.S. at 256.[16]

The labeling regulation promulgated by the FDA cannot even be remotely construed as preemptive in its language. As discussed, the FDA interprets the preemption provision found at 21 U.S.C. § 360k as not effecting state civil remedies in any regard.[17]

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[16]Likewise, in *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, this Court refused a party's invitation to do away with civil remedies on the thin justficiation that comprehensive federal regulation impliedly preempts: "To infer preemption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a result, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence." 471 U.S. 707 (1985), at 717. The comprehensive regulation Petitioner contends preempts Respondent's remedies is the Final Rule regarding tampon labeling, 21 C.F.R. § 801.430. Pet. App. 66a-67a.

[17]Petitioner cites the Court to several district courts who have held that a cause of action for failure to warn is preempted by Sec. 360k. Inexplicably, of those Courts who were informed of the existence of the FDA Advisory Opinion, none deigned to mention the Opinion in their memorandum decisions dismissing plaintiff claims for inadequate warning.

The lack of any persuasive support that the Food, Drug, and Cosmetic Act preempts state tort remedies impels the conclusion that this Court should not reach out to consider this issue in the face of the failure by the defendant-appellee to raise it before the trial court or the Tenth Circuit Court of Appeals.

———o———

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted,

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APPENDIX A

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IN THE SUPERIOR COURT OF
THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

BONNIE McCULLOUGH, a single woman,	No. C 539121
Plaintiff,	MOTION IN LIMINE
v.	(Oral Argument Requested)
THE PROCTOR & GAMBLE COMPANY, an Ohio corporation, et al.,	ASSIGNED TO THE HONORABLE
Defendants.	JEFFREY A. HOTHAM, DIV.50

COMES NOW Playtex Family Products, Inc. ("Playtex"), the successor to the tampon business of International Playtex, Inc. which was liquidated in December 1986, and moves *in limine* to exclude from trial any evidence (including live testimony, deposition testimony or exhibits) and any reference...

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

MARILYN BRIGGS,	)	
	)	
Plaintiff,	)	
vs.	)	No. CIV-85-C-450-E
	)	
INTERNATIONAL PLAYTEX, INC., a Corporation,	)	
	)	
Defendant.	)	

MOTION FOR PARTIAL SUMMARY JUDGMENT

COMES NOW the defendant, Playtex Family Products, Inc., the Successor to the tampon business of International Playtex, Inc., which was liquidated in December, 1986 (hereinafter Playtex), by and through its undersigned counsel, and moves this Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, for partial summary judgment as to all claims of the plaintiff for compensatory and punitive relief which are or may be premised upon allegations of an inadequate warning. In support of its Motion, Playtex submits its Memorandum in support filed contemporaneously herewith.

MONNET, HAYES, BULLIS,
THOMPSON & EDWARDS

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IN THE
UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

Nos. 85-1887, 85-1861

KELLY M. O'GILVIE, Individually and as Administrator of the Estate of Betty L. O'Gilvie, Deceased; and STEPHANIE L. O'GILVIE, a Minor, and KEVIN M. O'GILVIE, a Minor, By and Through Kelly M. O'Gilvie, Their Father and Natural Guardian,

Plaintiffs-Appellants,

-against-

INTERNATIONAL PLAYTEX, INC., a corporation,

Defendants-Appellee, Cross-Appellant.

CROSS-APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

CIV-83-1846

Patrick F. Kelly, District Judge

STIPULATION OF DISMISSAL OF MOTION OF PLAINTIFFS-APPELLANTS TO VACATE STAY OF MANDATE OR TO COMPEL FILING OF SUPERSEDEAS BOND

WHEREAS the parties have executed a supersedeas bond in the district court in the amount of $12,750,000, and have agreed to increase the amount of that bond to $15,000,000, the undersigned is authorized to request on behalf of all parties that the Motion of the Plaintiffs-Appellants to Vacate the Stay of Mandate or to Compel Filing of a Supersedeas Bond be dismissed as moot.

Respectfully submitted,

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Dated: January 15, 1988

APPENDIX B

UNITED STATES DISTRICT COURT
D. KANSAS

No. 83-1846-K

Kelly M. O'Gilvie, et al

Plaintiffs

v.

International Playtex, Inc. a Corporation

Defendant

(Filed February 26, 1985)

INSTRUCTIONS TO THE JURY

(Honorable Patrick F. Kelly, Presiding)

* * *

INSTRUCTION NO. 8

The burden of proof as to the issues before you lies with different parties. The burden is on the plaintiff to prove every element of a claim by a preponderance of the evidence. The burden is on the defendant to prove contentions of fault against the plaintiff or others.

A preponderance of the evidence means such evidence as, when considered and compared with that opposed to it, has more convincing force and produces in your minds a belief that what is sought to be proved is more likely true than not true. In other words, to establish a claim by a "preponderance of the evidence" merely means to prove that the claim is more likely so than not so, and not determined on conjecture, speculation or mere possibility.

In determining whether any fact in issue has been proved by a preponderance of the evidence, the jury may

consider the testimony of all the witnesses, regardless of who may have called them, and all the exhibits received in evidence, regardless of who may have produced them. If the proof should fail to establish any essential element of a claim of plaintiff by a preponderance of the evidence, the jury should find for the defendant as to that claim. Conversely, should the defendant fail to persuade you by a preponderance of the evidence as to its claim, you should find for plaintiff on that claim. The respective claims, and the burdens of proof as to each, are reviewed and defined in these instructions.

INSTRUCTION NO. 9

Kelly M. O'Gilvie, as surviving spouse and as administrator of the estate of Betty L. O'Gilvie, brings this suit on behalf of himself and his two children, Stephanie and Kevin. This is a products liability action for recovery of damages for the personal injuries and the wrongful death of Betty L. O'Gilvie.

The plaintiffs claim that Mrs. O'Gilvie's illness and resultant death were due to toxic shock syndrome in March and April of 1983, as a result of Mrs. O'Gilvie's use of Playtex products. The defendant, International Playtex, Inc., denies any liability for Mrs. O'Gilvie's illness and resultant death, and denies any causal relationship between the use of its product and toxic shock syndrome. The plaintiffs now sue International Playtex on two legal theories of liability: strict liability and negligence.

Under the theory of strict liability, the plaintiffs contend that Playtex tampons are defective in two ways. First,

plaintiffs contend that the Playtex tampons contain a design defect because the material components of the tampon, when placed in the environment of the human body, are a major contributing cause to the development of toxic shock syndrome. More specifically, plaintiffs claim that the higher absorbency qualities of the defendant's product increases the risk of toxic shock syndrome. Second, plaintiffs contend the Playtex tampons are defective because the label and instructions inside and outside the tampon box fail to provide to the consumer adequate instructions or warnings necessary for safe use of the product. That is, the plaintiffs contend that Playtex failed to adequately warn the consumer that there is a higher risk of developing toxic shock syndrome when using the super absorbent tampon. Additionally, the plaintiffs contend that defendant actually encouraged the use of a higher absorbency product.

The plaintiffs further contend that they should recover under the doctrine of strict liability in that defendant has misrepresented a material fact concerning the character or quality of its product and Mrs. O'Gilvie justifiably relied upon these misrepresentations.

The plaintiffs further contend that International Playtex is liable under the theory of negligence for three reasons. First, plaintiffs contend that International Playtex negligently failed to test the product to insure that the tampons were safe and would not cause or contribute to toxic shock syndrome. Second, plaintiffs contend that International Playtex negligently failed to warn consumers of the risk of developing toxic shock syndrome from Playtex tampons because the label and instructions are inade-

quate to warn and advise the consumer of the actual risk of toxic shock syndrome when using the product. Third, plaintiffs contend that International Playtex negligently designed the product by failing to insure that the product was safe for the use for which it was intended.

The plaintiffs' ultimate claim for damages is in the amount of $2,000,000.00.

Finally, plaintiffs contend that International Playtex is liable for punitive damages because International Playtex knew that super absorbent tampons were more likely to cause toxic shock syndrome but failed to warn the consumer of this risk, and in so doing acted in reckless and complete indifference to the probable consequences of its acts. The plaintiffs claim punitive damages in the amount of $10,000,000.00.

The defendant, International Playtex, Inc., on the other hand, contends that it is not liable for the personal injury or wrongful death of Mrs. O'Gilvie under any of the legal theories enumerated by the plaintiffs. At the outset, Playtex denies that Mrs. O'Gilvie was using its product. Next, defendant denies that there is any causal relationship between the use of the tampon and toxic shock syndrome. As to the theory of strict liability, International Playtex contends that there were no design defects in the product and there were no defects in the label or instructions. Simply said, International Playtex contends that there are no design defects in its product because Playtex tampons do not in any way contribute to the cause or to the development of toxic shock syndrome. Second, International Playtex contends that there are no defects in the tampon label and instructions because the alert statement

on the outside of the box and the instructions inside the box, provided in full compliance with certain federal drug administration (FDA) rules and regulations, fully and adequately informs the consumer of the association between tampons and toxic shock syndrome and the possibility of death resulting from toxic shock syndrome.

As to the theory of negligence, International Playtex contends that the company performed tests necessary to assure the safety of the use of Playtex tampons. Second, International Playtex contends that the company was not negligent in failing to warn because the label and instructions adequately inform the consumer of the association between tampon usage and toxic shock syndrome and the possibility of death resulting from toxic shock syndrome. Third, International Playtex contends that the company was not negligent in design because Playtex used at least ordinary care in the design of the tampon and the tampon is designed in such a manner that it is safe for the use for which it is intended.

Finally, International Playtex contends that it is not liable for punitive damages because Playtex never ignored the possible danger of toxic shock syndrome and never acted with a reckless disregard or indifference to the probability and consequences of its acts.

As indicated, International Playtex contends that the alleged use of Playtex tampons by Mrs. O'Gilvie did not in any way cause, contribute to, or aggravate her illness, and that Playtex tampons were not the direct or proximate cause of her illness. International Playtex contends that Playtex tampon use is neither a necessary nor a sufficient condition for the development of toxic shock syndrome.

Additionally, International Playtex contends that if it is found to be liable for the injuries and death of Mrs. O'Gilvie, its responsibility must be compared and reduced by the comparative fault of Betty O'Gilvie and/or Dr. Hays or his employees, and/or the Wichita Family Health Care, P.C., with whom he is engaged in practice. International Playtex contends that Dr. Hays was negligent in that he misdiagnosed Mrs. O'Gilvie when she first presented herself to Dr. Hays on March 30, 1983, and his negligence was the cause or a contributing cause of Mrs. O'Gilvie's injuries. In other words, defendant contends that had Dr. Hays timely diagnosed and/or treated Mrs. O'Gilvie for toxic shock syndrome, her injuries would have been minimal in that she probably would have survived. Playtex contends that Dr. Hays or his employees, and/or Wichita Family Health Care, P.C., were negligent in their failure to promptly and appropriately respond to Mrs. O'Gilvie and/or her family and friends' request for medical treatment, and this negligence was the cause or a contributing cause of Mrs. O'Gilvie's injuries.

International Playtex also contends that Mrs. O'Gilvie was at fault and her fault should be compared with the fault, if any, of International Playtex and the fault, if any, of International Playtex should be proportionately reduced. Playtex contends that Mrs. O'Gilvie was negligent because she was aware of the signs and symptoms of toxic shock syndrome and ignored the warnings and instructions that accompanied the Playtex tampons, and this conduct of Mrs. O'Gilvie was a contributing cause of her own illness and subsequent death. International Playtex contends that Mrs. O'Gilvie was aware of the risk of tampon

usage and assumed that risk and any subsequent injuries associated with said use.

The foregoing are merely the claims of the parties and are not to be considered as evidence.

INSTRUCTION NO. 10

As indicated, one legal theory under which plaintiffs contend that defendant is liable for the injuries to Mrs. O'Gilvie is the doctrine of strict liability in tort. The justification for this theory is the public policy that the burden of injuries caused by defective, unreasonably dangerous products placed on the market should be borne by the manufacturers and sellers of such products rather than by the consumers and users of such products. It is assumed that the manufacturers and sellers are in a better position than consumers to know whether their products are defective and unreasonably dangerous, and that if the manufacturers and sellers are held responsible for injuries caused by such products, they will analyze the products and their likely uses to minimize the likelihood of injury.

A manufacturer can be at fault under this theory even if it has taken all reasonable care in the preparation and sale of the product, and even if the user or consumer has not bought the product from the manufacturer. That is not to say that a manufacturer is automatically responsible to anyone who is hurt by that manufacturer's products. In this regard, the failure of a manufacturer of a product to adopt the most modern, or even a better safeguard, does not make the manufacturer legally liable to a person injured by that product. The manufacturer is not a guar-

antor that nobody will get hurt in using the product, and a product is not defective or unreasonably dangerous merely because it is possible to be injured while using it. There is no duty upon the manufacturer to produce a product that is "accident proof." What the manufacturer is required to do is to make a product which is free from defective and unreasonably dangerous conditions.

Now, as relates to the theory of strict liability in tort, you are instructed that a manufacturer of a product is at fault if:

1. The manufacturer was in the business of producing and selling the product;

2. The product was, at the time it left the manufacturer, defective and unreasonably dangerous to persons who might be expected to use the product;

3. The product was expected to and did reach the user without substantial change in the condition in which it was manufactured; and

4. The defect in the product caused or contributed to the injuries and damages of plaintiff.

Causation, as used here, means that the defective nature of the product is a substantial factor in bringing about harm. The terms "defective" and "unreasonably dangerous" are defined in instructions that follow.

With regard to plaintiffs' claim of misrepresentation, the Court has determined that insufficient evidence has been adduced to suggest recovery on this theory, and as a consequence, that part of plaintiffs' claim is not before you.

INSTRUCTION NO. 11

A product is in a "defective" condition if, at the time it leaves the manufacturer's hands, it is in a condition which is unreasonably dangerous to the ordinary user. A product is "defective" if, when it leaves the manufacture's hands, it is unsafe when used for a purpose for which it was intended, or when used for some reasonably foreseeable other purpose.

A product may be defective in its design, in its preparation, or by virtue of the inadequacies of the defendant's warnings necessary for the product's safe use.

INSTRUCTION NO. 12

A product is "unreasonably dangerous" if it is more dangerous than would be expected by the ordinary user of such a product, with the ordinary knowledge common to users of such a product. That is, a product is "unreasonably dangerous" if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it or uses it, with the ordinary knowledge common to the community as to its characteristics. In other words, a product is not "unreasonably dangerous" when its degree of danger is obvious or generally known and recognized; nor is it "unreasonably dangerous" if the manufacturer has given adequate warnings or instructions that sufficiently alert the user to the risk of danger in using the product.

A product may be unreasonably dangerous if the warning or label is not adequate to inform the consumer of the safe use of the product.

INSTRUCTION NO. 13

For a warning to be adequate, the content of the warning must be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a user.

If the content of the warning unreasonably minimizes the known dangers which exist, or gives false assurances to the consumer, then the warning is probably inadequate.

INSTRUCTION NO. 14

The Court has taken note of certain rulings of the Food and Drug Administration and has concluded that the warnings on the labels of defendant's product and the alert statement contained within the package are in conformity with these regulations.

INSTRUCTION NO. 15

If the warning on the product was, at the time of manufacture, in compliance with administrative regulatory safety standards relating to warnings or instructions, then such warning is evidence of due care, and the product shall be deemed not defective by reason of the warning or instructions, unless the plaintiff proves that a reasonably prudent manufacturer could and would have taken additional precautions.

In other words, you are instructed that even if you find that defendant International Playtex met all government regulations and requirements, which are minimum standards, such compliance is not a defense if a reasonable

and prudent manufacturer would have taken added precautions.

INSTRUCTION NO. 16

Simply said, the test here is whether the tampon product, taken together with the label and instructions inside and outside the box, was a defective and unreasonably dangerous product. In other words, was the Playtex tampon product, taken together with the label and instructions, more dangerous than that contemplated by an ordinary consumer who purchases the tampon, with the ordinary knowledge common to the community as to the characteristics of the tampon. If the tampon, along with the label and instructions, was more dangerous than that contemplated by an ordinary consumer, then the Playtex tampon was in a defective and unreasonably dangerous condition. If the tampon, along with the label and instructions, was not more dangerous than that contemplated by an ordinary consumer, then the Playtex tampon was not in a defective and unreasonably dangerous condition.

INSTRUCTION NO. 17

In order for the plaintiffs to recover from defendant Playtex on the plaintiffs' claim based on strict liability, you must find that all of the following have been proved:

1. The defendant is engaged in the business of manufacturing tampons;

2. The product was in a defective condition at the time it left the control of the defendant;

3. The product was expected to reach and did reach the hands of Betty O'Gilvie without substantial change in the condition in which it was manufactured.

4. The defect in the product was the cause or contributed to cause the toxic shock syndrome of Betty O'Gilvie and her resulting suffering and death.

If you find that the plaintiffs have not proved any one or more of these four elements by a preponderance of the evidence, then your verdict on this claim based on strict liability must be for the defendant, International Playtex.

However, on the other hand, if you find that the plaintiffs have proved all four elements by the preponderance of the evidence, then your verdict on this claim based on strict liability must be for the plaintiffs.

INSTRUCTION NO. 18

Turning next to plaintiffs' second theory of recover [sic], i.e., negligent manufacture, negligence is the lack of ordinary care under the existing circumstances. As applied to the manufacture, distribution, and sale of a product, it means the failure of a manufacturer to do something that a reasonably careful manufacturer engaged in the same business would do, or the doing of something by a manufacturer that a reasonably careful manufacturer engaged in the same business would not do. The degree of care must be equal to the danger reasonably to be anticipated, measured by all the facts and circumstances.

INSTRUCTION NO. 19

A manufacturer of a product has a duty to use ordinary care in the design of the product so that it will be reasonably safe for the use for which it is intended or

which can reasonably be anticipated. Failure to fulfill this duty constitutes negligence.

INSTRUCTION NO. 20

A manufacturer has a duty to make such tests and inspections, during and after the process of manufacture, as should be recognized as being reasonably necessary to secure the production of a safe product, and failure to do so constitutes negligence.

INSTRUCTION NO. 21

A manufacturer of a product which it knows, or by the exercise of ordinary care should know, is potentially dangerous to users thereof, has a duty to give adequate warning of such danger where injury to a user thereof can be reasonably anticipated if an adequate warning is not given. Failure to so warn constitutes negligence. Adequacy of warnings has been defined in previous instructions.

INSTRUCTION NO. 22

If you find International Playtex was negligent in the design, in the testing, or in the warning, then you must also determine whether the negligence was a legal cause of the damage to Mrs. O'Gilvie and her family.

A party's negligent conduct is a legal cause of harm to another if its conduct is a substantial factor in bringing about the harm.

A party is at fault when that person is negligent and that person's negligence caused or contributed to the event

which brought about the injury or damages for which claim is made.

Conversely, a party may be negligent in the conduct of that person's actions and such actions may not be contributing factors to the event.

INSTRUCTION NO. 26

An occurrence such as the injuries or death of Betty O'Gilvie may have several separate causes which combine, in various degrees, to bring about her injuries and death, or it may have a single cause to which the injuries are solely attributable. It may be that her injuries and death were as a consequence of the fault of no one. As indicated, you are asked to determine the extent to which International Playtex or Dr. Thomas Hays may have played a role, if any, in causing the injuries and death of Betty O'Gilvie.

Your first obligation is to determine whether Betty O'Gilvie was using defendant's product shortly before or at the time of her death. If you find she used the Playtex product, then you must determine which parties can be held at fault, that is, held legally responsible for Mrs. O'Gilvie's injuries and death. This is to be determined by the instructions previously set forth.

In this, you will first determine whether defendant International Playtex can be held causally responsible for plaintiffs' injuries and damages under any of the theories defined in these instructions, i.e., strict liability and/or negligence. If you find from the evidence that defendant

International Playtex was not causally responsible for plaintiffs' injuries, you will indicate this finding in your verdict. If you find defendant International Playtex has causal responsibility for plaintiffs' injuries, then you must determine whether Dr. Hays was also causally responsible in any degree. You must then assign a percentage reflecting each person's or company's causal contribution, if any, to the plaintiffs' injuries. The percentage you assign may range from zero percent (0%) to one hundred percent (100%). When the percentages assigned are added together, the total must equal one hundred percent (100%) if you find anyone causally responsible, or zero percent (0%) if you find no one causally responsible. You should keep in mind that the percentage of causal responsibility assigned to any should not be measured solely by the number of particular ways, if any, in which any has contributed to the injuries and death; nor should it be measured solely by the number of contributors to those injuries. You should, rather, weigh the contributions of all those mentioned above, determine whether one or more, or any, made a larger contribution than the others, and if so, to what extent.

I am required to apprise the jury that the laws of Kansas applicable to this case require me to reduce the amount of damages you have awarded to any party by the percentage of fault that you find is attributable to that party. This requisite, however, must not affect your assessment of damages should you find for plaintiffs in the case.

INSTRUCTION NO. 27

If you find for the plaintiffs under any theory of legal liability on the claim for the death of Betty O'Gilvie, two types of damages may be allowed as follows for her wrongful death. They are defined as pecuniary and non-pecuniary damages.

Nonpecuniary or limited damages include mental anguish, bereavement, loss of society and loss of companionship which you find has been and will be sustained by plaintiff Kelly O'Gilvie and the minor plaintiffs, Stephanie and Kevin O'Gilvie. Nonpecuniary damages are not easily measurable in monetary value. For these items of damage you may not allow more than $25,000.00, which is a limitation set by the Legislature.

Pecuniary damages are those reasonably measured in terms of money, and reasonably certain to have been lost or to be lost in the future. The damages will not include those found by you to be too speculative or remote to occur. There is no legislative limit on the amount you may allow for pecuniary or unlimited damages. This type of damage includes all items listed below:

1. Loss of service, attention, marital care, parental care, advice, and protection.

2. Loss of earnings you find the deceased would have provided to her husband, Kelly O'Gilvie.

3. Loss of financial support which you find the deceased, Betty O'Gilvie, would have provided to Stephanie and Kevin O'Gilvie during their minority.

4. Loss of educational, physical and moral training and guidance.

5. Expenses for the care of the deceased caused by her toxic shock syndrome.

6. Funeral expenses.

In other words, for these items of damage you should allow an amount which you believe will fairly compensate for plaintiffs' monetary losses already sustained or which you ....

* * *

INSTRUCTION NO. 30

If you find that plaintiffs are entitled to recover, and you also find that the conduct of the defendant was willful or wanton, then in addition to actual damages to which you find plaintiffs are entitled, you may award plaintiffs an additional amount as punitive damages in such sum as you believe will serve to punish defendant and deter others from like conduct.

INSTRUCTION NO. 31

In order for plaintiffs to recover punitive damages for willful or wanton conduct, it is not necessary that their evidence establish a formal and direct intention to injure any particular person. It is sufficient if you find from the preponderance of the evidence a degree of indifference to the rights of others which may justly be characterized as reckless. Reckless is indifference whether wrong is done or not, and is a stronger term than ordinary negligence. To be reckless, conduct must be such as to evince disregard of or indifference to consequences, under cir-

cumstances involving danger to life or safety of others, although no harm was intended.

In order to assess punitive damages in this case, you must find that a company official with authority to act had been apprised of sufficient significant medical findings, including competent epidemiologic and microbiologic data from which the official knew or should have known that the company ought to act to more adequately warn or otherwise decrease the risk of danger, and consciously elected not to act.

The Court has submitted certain special interrogatories which are designed to test the jury's understanding of the evidence with their specific responses. Additionally, it is intended that this practice will be helpful to the jury, particularly should it elect to consider punitive damages.

* * *

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

Case No. 83-1845

Volume No. 37

Kelly O'Gilvie, et al.,

Plaintiffs

v.

International Playtex, Inc.

Defendant

POST-TRIAL MOTIONS AND COURT'S FINDINGS

On the 21st day of March, 1985, came on to be heard Post-Trial Motions and Rulings in the above-entitled and numbered cause before the HONORABLE PATRICK F. KELLY, Judge of the United States District Court for the District of Kansas, Sitting in Wichita.

APPEARANCES:

The Plaintiffs appeared by and through Gerald Michaud and Mark Hutton;

The Defendant appeared by and through Charles McCaghey, Larry Wall and Glen Pogust.

* * *

(p. 3521) MR. McCAGHEY: Judge, I think the verdict is saying go on appeal to Playtex, Judge.

THE COURT: You don't think they are saying Change your product?

MR. McCAGHEY: I'm not sure. Judge, I don't want to get into trying to figure out why the jury decided that. If we are talking about the ten million, Your Honor, I think the dollar amount shocks the conscience. You have a company here, Judge, that is using the same warnings as all of its competitors, warning approved by the FDA, no one suggesting the product should come off the market, no one has told this company what it should do now in terms of changing that product in the scientific community, Judge.

THE COURT: This jury verdict is saying, who heard the scientific community as clearly as you will ever hear if you try this case a dozen times, Mr. McCaghey, that you're wrong; this product causes toxic shock and your company knows it. That's what they said in that verdict by their answer, right?

MR. McCAGHEY: Judge, that may well be what they say but that jury might be wrong too after everything is said and done.

(p. 3522) THE COURT: All right.

MR. McCAGHEY: In terms of the ten million dollars, I think it does shock the conscience. I think to subject a company to this type of punitive damage award which can be repeated one after another in cases across the land is wrong, I don't think it is justified. If you ask me what dollar amount should it be, well, you know my ultimate answer to you is you need no dollars.

THE COURT: Should it be a sum that the company with the income and assets of Playtex would absorb as a cost of doing business and move on?

MR. McCAGHEY: Judge—

THE COURT: Or is it sum that makes this company say: We better listen. We better do something. We better change?

MR. McCAGHEY: Judge, this company is going to listen to what comes down by way of verdicts, et cetera, regardless of the sum. Now, I think you already have a sum in hand and—

THE COURT: I think the jury gave you a sum in hand that surely ought to say you better listen.

MR. McCAGHEY: I'm sure this company, Judge, will listen to this verdict regardless of what the dollar amounts of it are.

THE COURT: I wonder if they are listening to (p. 3523) the extent that if I'm correct that you are collaterally estopped to raise again causation, we have five cases pending here with your company and punitive damages will continue to go to the jury until I hear you say you have got their attention. There has to come a time, Mr. McCaghey, when this company will listen, isn't there? What do you think this verdict is saying?

MR. McCAGHEY: Pardon me.

THE COURT: What do you think this verdict is saying? Is it saying: Change, stop what you're doing, you're killing people. Take the product off of the market. Is that what they are saying?

MR. McCAUGHEY: May well be saying that to them. I'm not suggesting to you that it is not. You have to understand that I'm not in a position here where I'm going to concede to the validity of that verdict. I personally feel it is improper and I personally feel ten million dollars shocks the conscience and that it should be either done away with totally or there be a remittitur on it.

THE COURT: That's why we are here. I have given serious thought to it, Mr. McCaghey, and I'm the first to agree that it is a substantial sum, but I also accept this jury's verdict. This product does cause toxic shock and death, contents of your product, polyacrylate, does increase that risk, your warnings are inadequate, your company knows it, or (p. 3524) should have known it, and has done nothing. Now what is it that is sufficient but to say that to know? Shouldn't be a sum that is accepted or absorbed as a cost of doing business. I think it ought to be enough that makes somebody with authority to change.

I think this jury's verdict is really saying: Playtex, take that damnable product off the market, you're killing people with it; it's inadequate in its warnings, change. I think it's saying: Go back to FDA and explain to them that we are ready to change, and that the FDA is wrong, they have not had what this jury heard. I think that's what they are saying with regard to the verdict.

If you will, as to this amount, it is a substantial sum. This jury heard something about Playtex Company, its assets and earnings. In my view and in light of their findings, as I understand it and accept it, there is nothing

criminal or punitive nor unconstitutional about it. It is no more than the voice of this jury, voice of this community saying: Stop it. They weighed the enormity of the wrongdoing and that's what that verdict intends to say.

I have to say to you that the amount of the verdict does not bother me, nor shock my conscience, and in light of the findings this jury made I'm not surprised with it. I'm frank to say that I recall Mr. Michaud had asked to increase the prayer to twenty million dollars and I denied it for the (p. 3525) reasons we took up, which also offended him. Had this gone to the jury for twenty million dollars, it would not have surprised me had they entered such a verdict and it also would stand.

With that said, this jury's verdict as to punitive damages will presently stand. It is the product of a fully tried case, well prepared by able counsel to a fair and impartial jury who heard it all, who understood the duty and performed, as I said to them as I discharged them, superbly. They truly are the conscience of our community. They reached their decision and if I understand their answer, they had no other choice, and that verdict for this reason will not be touched by this Court.

Let me make an aside having said that to you: Punitive damages in the present state of our law, rightly or wrongly, is truly the only way the jury can express itself, if you will, to express its outrage or to attempt to communicate punishment or deterrence. I'm convinced, Mr. McCaghey, this jury is saying: Change. Take that polycrylate rayon product off the market. It is killing people. It's increasing the risks of it, and your company knows it, and change.

As you and I both know this jury nor is this Court authorized to follow through with that. Certainly when I find that the verdict is not excessive, I have no real authority with which I'm aware to do anything. I can't order them to (p. 3526) seize or desist, nor can I order an FDA hearing that would surely follow if they accepted this jury's verdict as I have heard it. If you will, others can.

* * *

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

KELLY M. O'GILVIE, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	
	)	No. 83-1846-K
INTERNATIONAL PLAYTEX, INC.,	)	
	)	
	)	
Defendant.	)	
	)	

REQUESTED JURY INSTRUCTIONS OF
DEFENDANT INTERNATIONAL PLAYTEX, INC.

INSTRUCTION NO. 2

The burden of proof as to the issues before you lies with different parties. Burden of proof means burden of persuasion. A party who has the burden of proof must persuade you that his claim is more likely so than not. In determining whether or not a party has met this burden, you will consider all the evidence, whether produced by plaintiff or defendant.

Plaintiff has the burden of proof to show all the elements necessary to hold the defendants causally responsible, in whole or in part, under the theory that defendant acted negligently and is responsible for his damages, or that defendant is strictly liable for the claimed damages.

Defendant has the burden of proof to show all the elements necessary to hold plaintiff's wife, Betty O'Gilvie,

or Dr. Hays or others, causally responsible, in whole or in part, under the theory of their own negligence, or Mrs. O'Gilvie's assumption of the risk and negligent misuse of the product.

In determining whether any fact in issue has been proved by a preponderance of the evidence, the jury may consider the testimony of all the witnesses, regardless of who may have called them, and all the exhibits received in evidence, regardless of who may have produced them. If the proof should fail to establish any essential element of plaintiff's claim by a preponderance of the evidence, the jury should find for the defendant as to that claim.

PIK 2.10, 2.20 and 6.01 (modified)
Andersen v. Nation, et al.

INSTRUCTION NO. 9

A manufacturer of a product which knows, or by the exercise of ordinary care should know, is potentially dangerous to users thereof, has a duty to give adequate warnings of such danger where injury to a user thereof can be reasonably anticipated. Failure to so warn constitutes negligence.

If the warning on the product was, at the time of manufacture, in compliance with administrative regulatory safety standards relating to warnings or instructions, the product shall be deemed not defective by reason of the warning or instructions, unless the plaintiff proves that a reasonably prudent manufacturer could and would have taken additional precautions.

You are further instructed that any duty to warn against a danger or hazard does not extend:

(1) To warnings, protecting against or instructing with regard to those safeguards, precautions, and actions which a reasonable user or consumer of the product, with the experience, education, and with any special knowledge the user or consumer did, should or was required to possess, could and should have taken for such user or consumer or others, under all the facts and circumstances;

(2) To situations where the safeguards, precautions, and actions would or should have been taken by a reasonable user or consumer of the product similarly situated exercising reasonable care, caution, and procedure.

PIK 13.05 (modified)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

KELLY M. OGILVIE, et al., Plaintiffs, vs. INTERNATIONAL PLAYTEX, INC., Defendant.	)	Civil Action No. 83-1846

DEFENDANT'S REQUESTED
SPECIAL INTERROGATORIES TO THE JURY

1. Was Mrs. O'Gilvie wearing Playtex super deodorant tampons immediately before and during the time she first became ill in March of 1983?

Yes_____ No_____

If the answer is no, you need not answer the remaining questions.

2. Did any Playtex super deodorant tampon cause Mrs. O'Gilvie to become sick with toxic shock syndrome?

Yes_____ No_____

If the answer is no, you need not answer the remaining questions.

3. If yes, did any other brand or brands of tampons also cause her to become ill?

Yes_____ No_____

4. Did Playtex adequately warn consumers of the risk of toxic shock syndrome in wearing its tampons?

Yes———— No————

If the answer is yes, you need not answer the remaining questions.

5. Did Mrs. O'Gilvie know or should she reasonably have known that tampon use presents a risk of menstrually related toxic shock syndrome?

Yes———— No————

If the answer is yes, you need not answer the remaining questions.

6. Is the Playtex super deodorant tampon defective or unreasonably dangerous?

Yes———— No————

If the answer is no, you need not answer the remaining questions.

7. Could Playtex have manufactured a tampon that was free from risk of toxic shock syndrome?

Yes———— No————

If the answer is no, you need not answer the remaining questions.

8. Was Playtex aware in March, 1983, that it could manufacture a tampon that was free of risk of toxic shock syndrome and chose not to do so?

Yes———— No————

If the answer is no, you need not answer the following question.

9. Was Playtex guilty of willful, wanton, conscious and reckless disregard of Mrs. O'Gilvie's rights necessitating an award of punitive damages?

Yes———— No————

APPENDIX E

STATUTES

Kansas Statutes Annotated, Section 21-4503 (1985)

Fines. (1) A person who has been convicted of a felony may, in addition to or instead of the imprisonment authorized by law, be sentenced to pay a fine which shall be fixed by the court as follows:

(a) For a class B or C felony, a sum not exceeding $15,000.

(b) For a Class D or E felony, a sum not exceeding $10,000.

(2) A person who has been convicted of a misdemeanor may, in addition to or instead of the confinement authorized by law, be sentenced to pay a fine which shall be fixed by the court as follows:

(a) For a class A misdemeanor, a sum not exceeding $2,500.

(b) For a class B misdemeanor, a sum not exceeding $1,000.

(c) For a class C misdemeanor, a sum not exceeding $500.

(d) For an unclassified misdemeanor, any sum authorized by the statute that defines the crime; if no penalty is provided in such law, the fine shall not exceed the fine provided herein for a class C misdemeanor.

(3) As an alternative to any of the above fines, the fine imposed may be fixed at any greater sum not exceed-

ing double the pecuniary gain derived from the crime by the offender.

(4) A person who has been convicted of a traffic infraction may be sentenced to pay a fine which shall be fixed by the court not exceeding $500.

APPENDIX F

FOOD AND DRUG ADMINISTRATION

Advisory Opinion

March 8, 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You have requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the

force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. Under section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern the legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to a device only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in *National*

Women's Health Network, et al. v. A.H. Robins Company, Inc., No. 81-000D4-N (D. Mass filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injunctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachusetts or any other State.

Sincerely yours,

/s/ Joseph P. Hile
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: Jeanne Baker, Esq.
David Fine, Esq.
Silverglate, Gertner, Baker & Fine
88 Broad Street
Boston, Massachusetts 02110